

## **REMARKS**

### ***Status of the Claims***

By this Amendment, claims 1-23 are canceled, and new claims 24-28 are added. Accordingly, new claims 24-28 are pending, with claim 24 being independent.

Applicants note that in the Office Action mailed February 9, 2005, the Examiner rendered an analysis based on a search of compounds of formula (I) and compositions thereof wherein  $R^1$  and  $R^2$  are independently hydrogen or hydroxyl; X is hydroxyl; Z is  $-M-Q^{X'}$  wherein M is  $-\text{CH}_2\text{CH}_2\text{C}(\text{O})-$  and  $Q^{X'}$  is  $-\text{I}'_{i'}-\text{J}'_{j'}-\text{D}'-\text{K}'_{k'}-\text{R}^{40'}$  wherein  $j'$  and  $k'$  are zero;  $\text{I}'$  is  $[\text{NR}^{50'}-(\text{CR}^{51'}\text{R}^{52'})_a-(\text{CR}^{53'}\text{R}^{54'})_b-\text{C}(\text{O})]$ , wherein one of  $a$  or  $b$  is 1 and the other is zero (*i.e.*, an  $\alpha$ -amino acid),  $\text{R}^{40'}$  is hydroxyl, and  $\text{D}'$  is a drug, including ampicillin, containing a heterocyclic ring system and at least one carboxylic acid group (Office Action, paragraph 2).

New claims 24-28 have been added to include those portions of claims 1, 3, 4, 6, 8, 9, 18, 20 and 23 to the extent that they read on the elected and above-searched compounds as defined by the Examiner. Thus, this amendment is fully supported by the specification as originally filed and adds no new matter.

Claims 1-23 have been canceled as containing non-elected subject matter without prejudice to or disclaimer of the subject matter contained therein. Applicants have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and following remarks.

### **Rejections under 35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 1, 3, 4, 6, 8, 9, 18, 20 and 23 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claiming the subject matter which the Applicants regard as their invention.

Applicants' cancellation of claims 1, 3, 4, 6, 8, 9, 18, 20 and 23 renders moot the Examiner's rejection of these claims under 35 U.S.C. § 112, second paragraph, as recited in paragraphs 5(b) to 5(e) of the Office Action.

The Examiner has rejected claims 1 and 18 under 35 U.S.C. § 112, second paragraph as indefinite for not clearly reciting what a drug is (Office Action 5(a)). Applicants note that claims 1 and 18 are now canceled and new claim 24 instead recites that D' is "a pharmacologically active chemical compound." The language of claim 24 is believed to address the Examiner's indefiniteness rejection as recited in paragraph 5(a) of the Office Action.

New claim 24 recites that D' is a chemical compound "containing at least one carboxylic acid group and at least one moiety selected from the group consisting of a primary amino group, a secondary amino group or a hydroxyl group." Compounds within the scope of D' are clearly identified by structural properties such that one skilled in the chemical arts could readily determine whether a particular compound "contained at least one carboxylic acid group, and at least one moiety selected from the group consisting of a primary amino group, a secondary amino group or a hydroxyl group", and one of skilled in the chemical arts could also readily determine whether the compound is pharmacologically active. Accordingly, one of skilled in the chemical arts could readily establish whether the compound is encompassed by the present claims. Carboxylic acid, primary amino, secondary amino and hydroxyl groups are simple chemical moieties that have a clear and definite meaning to a chemist. Thus, the language used to claim the element D' in claim 24 provides a reasonable degree of clarity to enable one skilled in the chemical arts to understand the claim elements and to readily determine which compounds fall within the scope of the present claims.

On pages 35-36 of the specification, Applicants disclose several examples of pharmaceutically active compounds representative of D'. Applicants disclose thirty four (34) pharmaceutically active compounds containing a carboxylic acid group and at least one hydroxyl group, including enalaprilic acid, quinaprilat, cefadroxil, cefatrizine, cefbuperazone, cefonicid, cefoperazone, cefpimizole, cefsulodin, cefpiramide, ceftazidime, ceftriaxone, latamoxef, amoxycillin, apalcillin, carbenicillin, sulbenicillin, zanamivir, BCX-1812, diflunisal, salicylic acid, salicylsalicylic acid, ciprostone, 16-

dexoy-16-hydroxy-16-vinyl prostaglandin E<sub>2</sub>, 6, 16-dimethylprostaglandin E<sub>2</sub>, nileprost, prostacyclin, prostaglandins E<sub>1</sub>, E<sub>2</sub> or F<sub>2α</sub>, thromboxane A<sub>2</sub>, aztreonam, imipenem, and meropenem. Applicants also disclose thirty five (35) pharmaceutically active compounds containing a carboxylic acid group and at least one primary amino group including lisinopril, cefaclor, cefadroxil, cefatrizine, cefixime, cefmenoxime, cefodizime, ceforanide, cefotaxime, cefotefan, cefotiam, cefoxitin, cefpirome, cefpodoxime, cefroxadine, cefsulodin, ceftazidime, ceftizoxime, ceftriaxone, cefuroxime, cephalixin, cephalglycin, cephradine, amoxycillin, ampicillin, cyclacillin, dicloxacillin, epicillin, argatroban, melagatran, napsagatran, zanamivir, BCX-1812, enoxacin, and aztreonam. Applicants further disclose eighty five (85) pharmaceutically active compounds containing a carboxylic acid group and at least one secondary amino group including alecapril, enalaprilic acid, lisinopril, quinaprilat, tiopronin, cefaclor, cefadroxil, cefamandole, cefatrizine, cefazedone, cefazolin, cefbuperazone, cefixime, cefmenoxime, cefmetazole, cefodizime, cefonicid, cefoperazone, ceforanide, cefotaxime, cefotefan, cefotiam, cefoxitin, cefpimizole, cefpirome, cefpodoxime, cefroxadine, cefsulodin, cefpiramide, ceftazidime, ceftazole, ceftizoxime, ceftriaxone, cefuroxime, cephacetrile, cephalixin, cephaloglycin, cephradine, latamoxef, amoxycillin, ampicillin, apalcillin, azidocillin, azlocillin, benzylpenicillin, carbenicillin, carindacillin, cloxacillin, cyclacillin, dicloxacillin, epicillin, flucloxacillin, hetacillin, methicillin, mezlocillin, nafcillin, oxacillin, phenethicillin, piperazillin, sulbenicillin, temocillin, ticarcillin, argatroban, melagatran, napsagatran, zanamivir, BCX-1812, alminoprofen, carprofen, clonixin, diclenofac, etodolac, flufenamic acid, flutiazin, meclofenamic acid, mefenamic acid, nifluminic acid, prodolic acid, tolfenamic acid, ciprofloxacin, norfloxacin, pipemidic acid, aztreonam, imipenem, and meropenem.

In view of the large number of representative compounds illustrating the scope of D', a chemist could readily identify other compounds encompassed by the genus, D'. Furthermore, Applicants respectfully assert that while D' potentially includes a large number of compounds, as long as the scope is clear, the claim complies with 35 U.S.C. § 112, second paragraph (*MPEP*, 2173.04, page 2100-207, Rev. 2, May 2004, *citing In re Miller*, 441 F.2d 689 (CCPA 1971)).

Also in claim 24, certain compounds within the scope of the provisos are excluded from D'. The meaning of each of the groups of compounds excluded by the proviso are clearly defined in the specification. For example, GABA analogs are disclosed on page 41, line 1 to page 43, line 3; L-aromatic amino acid decarboxylase inhibitors are disclosed on page 43, line 17 to page 44, line 13; catechol O-methyl transferase inhibitors are disclosed on page 43, lines 4-16; naturally occurring  $\alpha$ -amino acids are disclosed on page 35, lines 1-7; linear oligopeptides are disclosed on page 45, lines 10-20; HMG-CoA reductase inhibitors are disclosed in the references provided on page 5, lines 1-4; and proline hydroxylase inhibitors are disclosed in Kramer, et al., U.S. Patent No. 5,646,272, cited on page 107, lines 16-17. L-Dopa, oligonucleotides (see, for example, IUPAC Compendium of Chemical Terminology, 2<sup>nd</sup> Edition 1997), cyclophane derivatives (see, for example, IUPAC Compendium of Chemical Terminology, 2<sup>nd</sup> Edition 1997), diethylenetriaminopentaacetate derivatives or paramagnetic chelates thereof, 5-de-O-methylsporadicin, and bis-(2-chloroethyl)amine containing nitrogen mustards (see, for example, IUPAC Compendium of Chemical Terminology, 2<sup>nd</sup> Edition 1997), and Applicants', definition of "derivatives" on page 46, line 1-12, refer to either specific compounds or include chemical compounds which can be ascertained with a reasonable degree of clarity by one skilled in the art.

For at least these reasons, Applicants respectfully request that the Examiner conclude that new claim 24 is not indefinite under 35 U.S.C. § 112, second paragraph.

#### **Rejections under 35 U.S.C. § 102(a) over Okada**

The Examiner has rejected claims 18 and 23 under 35 U.S.C. § 102(b) as allegedly being anticipated by Okada (JP 11-60594). Claims 18 and 23 have been canceled without prejudice to or disclaimer of the subject matter contained therein as directed to non-elected subject matter, thereby rendering moot the Examiner's rejection of the claims under 35 U.S.C. § 102(b). Accordingly, Applicants respectfully request that this rejection be withdrawn.

***Conclusion***

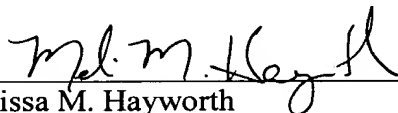
Without conceding the propriety of the rejections, the claims have been amended, as provided above, to even more clearly recite and distinctly claim Applicants' invention and to pursue an early allowance. For the reasons noted above, the art of record does not disclose or suggest the inventive concept of the present invention as defined by the claims.

In view of the foregoing remarks, reconsideration of the claims and allowance of the subject application is earnestly solicited. In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

In the event any further fees are due to maintain pendency of this application, the Examiner is authorized to charge such fees to Deposit Account No. 02-4800.

Respectfully submitted,

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